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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/773,394	01/31/01	WIKLUND	P/2432-37

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OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK NY 10036-8403

EXAMINER	
BAHAR,M	
ART UNIT	**PAPER NUMBER**
1617	4

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application N .	Applicant(s)	
	09/773,394	WIKLUND ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's amendments and response to the first office action of April 10, 2001, submitted July 13, 2001 (Paper No. 3) is acknowledged.

Applicant's amendment has been considered and is persuasive to overcome the objections as well as the rejections under 35 USC 101 and 103 (over 5,719,118) of claims 7-14 in the previous office action.

Claims 1-2 and 4-21 are herein examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 15, the expression "an amount effective to preserve skeletal muscle" is indefinite since one of ordinary skill in the art would not know what effective amount is referred to, e.g., the first recited composition, second recited composition or some combination of the two.

Applicant's arguments submitted July 13, 2001 regarding the expression of amounts in functional terms has been considered, but is not persuasive to remove the rejection because the indefiniteness of the claim lies in the fact that it is unclear as to what (i.e., composition and/or combination) the "effective amount" is referring, not only in the expression of amounts.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Veech (USPN 5,719,119).

Veech (USPN 5,719,119) teaches that normal plasma contains concentrations of ammonium ions x [alphaketoglutarate]/[glutamate]. Veech also teaches alpha ketoglutarate and ammonium in an amino acid solution containing glutamate which can control the redox state of the mitochondria, see col. 13 line 66 to col. 14 line 20. Carriers taught in the reference are useful for infusion or oral compositions. See table 9, and columns 20-21.

Applicant's arguments submitted July 13, 2001 regarding the Veech reference have been considered but are unpersuasive. The applicant argues that Veech contains more components than those in the instant claims. Note that the claim language recites the open transitional phrase "comprising" and therefore any composition that includes the claimed components—whether it includes additional active ingredients (as in Veech) or not—will read on the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 and 4-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feliciano in view of Weisiger and applicant's admissions regarding the prior art on pages 1-2 in the specification.

Feliciano teaches that the salts of alpha ketoglutarate have been demonstrated to increase muscle glutamine stores in severely catabolic hospital patients. Feliciano also teaches that alpha ketoglutarate is utilized in the Krebs cycle and provides the carbon skeleton for a portion of glutamine synthesis. These processes are important for muscle metabolism and immune function during periods of physical stress, see particularly page 3.

Feliciano does not teach the incorporation of ammonium chloride along with alpha ketoglutarate in catabolic hospital patients. Neither does it teach the particular salts of ammonium or alpha-ketoglutarate to be used in its solution/composition, nor does Feliciano teach the dosing rate of each compound.

Weisiger teaches that glutamate is formed from ammonium ion and alpha ketoglutarate, see page 770 last paragraph.

The applicant teaches that Ammonium Chloride is known to be administered to patients in pharmaceutical compositions, see page 2 of the specification. Applicant also admits that during postoperative and post-traumatic catabolism glutamine's availability is decreased, see page 1, lines 6-11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to concomitantly employ alpha ketoglutarate and ammonium (or any salts thereof) in a compositions consisting essentially of the same to be used in catabolic patients and to administer the compounds at the claimed dosing rates.

One of ordinary skill in the art would have been motivated to concomitantly employ alpha ketoglutarate and ammonium (or any salts thereof) in compositions consisting essentially of the same to be used in methods of preserving the bodily protein of catabolic patients because ammonium ions and alpha ketoglutarate (a precursor of glutamine) are known to form glutamate thereby eliminating the body's need to break down its own protein as an energy source. The employment of salts of known pharmaceutical agents is seen to be within the skill of the artisan. Optimization of amounts and dosing rates is within the skill of the artisan, absent evidence to the contrary.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (USPN 5,719,119) in view of applicant's admissions in the specification section entitled "Background of the Invention," pages 1-3, particularly page 2 (rejection already of record in the previous office action)

Veech (USPN 5,719,119) teaches that normal plasma contains concentrations of ammonium ions x [alphaketoglutarate]/[glutamate]. Veech also teaches alpha ketoglutarate and ammonium in an amino acid solution containing glutamate which can control the redox state of the mitochondria and therefore be useful in nitrogen-containing pharmaceutical compositions , see col. 13 line 5 to col. 14 line 20.

Veech (USPN 5,719,119) does not teach the particular salts of ammonium or alpha-ketoglutarate to be used in its solution/composition.

The applicant teaches that Ammonium Chloride is known to be is administered to patients in pharmaceutical compositions, see page 2 of the specification.

It would have been obvious to one of ordinary skill in the art at the time invention was made to use the recited salt of ammonium and alpha-ketoglutarate in Veech's solution. One of ordinary skill in the art would have been motivated to use any known pharmaceutically acceptable salts of ammonium and alpha-ketoglutarate since the selection of known pharmaceutically acceptable salts of actives is considered within the skill of the artisan.

The newly added claims 20-21 have substantially the same scope of original claims 18-19 in the previous office action.

Possible unexpected results over the prior art employing alpha ketoglutarate along with an ammonium salt in a catabolic patient have been considered but are not found persuasive because the concomittant employment of an ammonium salt and alpha ketoglutarate would have been expected to be useful to preserve the bodily protein of a catabolic patient based on the cited prior art. It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Applicant has the burden to explain how the data presented in tables 1.1 and 1.2 are relevant to showing of unexpected results in the prior art. Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, no convincing and clear unexpected result is seen given the error rates (standard deviations) presented in data, note especially for example page 29, Table 3.1.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
September 21, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600